REMARKS/ARGUMENTS

Claims 1-22 and 29-42 remain pending in the application. Prior claims 1-42 were rejected. By way of the present amendment, claims 1, 5, 9, 10, 15, 19, 24, 27, 41, and 42 have been amended, claim 23 has been cancelled, and no new claims have been added. Applicants request entry of this amendment and reconsideration of the claims given the amendments and remarks made herein.

Claim Rejections - 35 USC §112

Claim 42 was rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement. [Office Action page 4]. Claims 32 and 42 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite. Such rejections are traversed in part and overcome in part. More specifically, the "complementary" language has been canceled from claim 42. Hence, the rejection of that claim is now moot.

Regarding the scaling of an ablation zone to a pupil diameter, Applicants have amended the specification to explicitly recite information previously incorporated by reference in paragraph [0030] of the originally-filed specification for the subject invention. The language added to the specification has been taken word-for-word from the disclosure of Application No. 10/738,358, which has since issued as U.S. Patent No. 7,293,873 (with the language being taken from Col. 32, lines 25-38 of that patent). Hence, no new matter has been added.

For the Examiner's convenience, Applicants are also attaching as an appendix a page from the textbook *The Excimer Manual: A Clinician's Guide to Excimer Laser Surgery* (Jonathan H. Talamo, M.D., et al.) (1997). As noted in this well-known text, "Pupil size and shape are especially important when planning the optical zone size for RK or photoablative procedures." [*Id,* page 40]. Pupil size has been measured for well over the last decade as a basic screening parameter for patients considering laser eye surgery, with these pupil measurements often being performed under scotopic conditions using an infrared video camera with pupil detection (such as the Procyon™ Pupillometer), infrared tubes with a retical or display (such as the Colvard™ or Pupilscan™ systems), and/or gauges (such as a Holladay™ pupil gauge or a

Rosenbaum card), or the like. Also for the Examiner's convenience, an article entitled "Focus on Pupillometers" from Ophthalmology Management of May 2004 is attached hereto. Based on these references, and on the knowledge of those in the field shown by these references for how to use pupil diameter as a basic gating parameter and input to laser eye surgery systems, Applicants respectfully request that the rejection of claim 32 be removed, and that the claims be allowed.

Claim Rejections - 35 USC §102

Prior claims 1-3, 5, 9, 11, 14-17, 19, 23-24, 26, and 41-42 were rejected under 35 USC §102(b) as allegedly anticipated by US 6,312,424 in the name of Largent (hereinafter "Largent"). [Office Action pages 5-6] Such rejection is traversed in part and overcome in part as follows.

Applicants have amended independent claim 1 to recite ablating a first eye so that an ablated central zone has a near optical power and a peripheral zone has a far optical power which is less than the near optical power. Similarly, claim 1 also recites ablating a second eye of that same patient so that a peripheral zone of the second eye has a near optical power, while a central zone of the second eye has a far optical power. Moreover, Applicants have explicitly recited in claim 1 that the central zones of each eye encompass a pupil center of that eye. Applicants respectfully submit that there is no disclosure whatsoever in Largent that would provide a reasonable basis for those of skill in the art to treat presbyopia of a single patient by providing optical powers of the two eyes such that the patient views near objects through a central portion of one eye and a peripheral portion of the other eye, while viewing far objects through a peripheral portion of the one eye and a central portion of the other eye. Applicants note that the central portions of two eyes treated using the Largent approach would be expected to view both near objects with the same portions of both eyes, and view far objects with corresponding portions of both eyes. Hence, notwithstanding any alternating near/far power variation in Largent, the elements of amended independent claim 1 support patentability of that claim as there is no articulated basis of record for modifying the Largent treatment method.

Regarding amended independent claim 15, that claim recites determining a first ablative shape for a corneal surface that provides an optical power that varies so as to enhance

vision of near objects through a central zone, and so as to be suitable for vision of far objects through a peripheral zone. A first eye of the patient is ablated according to the first ablative shape, and a second ablative shape is determined that provides an optical power that varies so as to enhance vision of the near objects through a peripheral zone of an eye, and so as to be suitable for vision of the far objects through a central zone of the eye. A second eye of the patient is ablated according to the second ablative shape, with the first and second ablative shapes mitigating presbyopia. Hence, claim 15 recites that a central portion of one shape provides for near vision, while the central portion of another shape provides far vision for the same patient. This combination of elements is nowhere to be seen in Largent, so that claim 15 is allowable.

Regarding the dependent claims, they are allowable as depending from allowable independent claims, as well as for the novel combinations of elements recited therein. For example, dependent claim 10 recites that the peripheral zone of the first eye extends radially outward to a diameter approximately matching an outer scotopic boundary of the pupil of the first eye. Similarly, claim 10 also recites that the peripheral zone of the second eye extends radially outward to a diameter approximately matching an outer scotopic boundary of the pupil of the second eye. Hence, these peripheral zones (suitable for near vision for one eye, and far vision for the other eye) perform different functions for a single patient, notwithstanding their similar locations on their associated eyes. Such a structure is nowhere to be seen in Largent.

Claim Rejections - 35 USC §103

Claims 4, 6-8, 10, 12-13, 18, 20-22, and 25 are rejected under 35 USC §103(a) as allegedly unpatentable over Largent. [Office Action page 6] Prior claims 27-30, 32, 36-37, and 39-40 are rejected under 35 USC §103(a) as allegedly unpatentable over Largent in combination with US 6,364,873 in the name of McMillen et al. (hereinafter "McMillen"). [Office Action page 6] Prior claims 31, 33-35, and 38 are rejected under 35 USC §103(a) as allegedly unpatentable over Largent in combination with McMillen. [Office Action pages 6-7] Such rejections are traversed in part and overcome in part as follows.

Independent claim 27 recites a laser eye surgery system having a processor that directs energy to ablate a first ablative shape on a corneal surface of a first eye of a patient and a

second ablative shape on a corneal surface of a second eye of the patient. Each ablative shape has an optical power that varies across the corneal surface, with the first ablative shape enhancing near vision through a central zone of the first eye while enhancing far vision through a peripheral zone of the first eye. The optical power of the second ablative shape enhances near vision through a peripheral zone of the second eye, while enhancing far vision through a central zone of the second eye. As the originally-filed specification for the present invention indicates, patients having presbyopia benefit from significant variations in optical powers to provide near and far vision. No prior art reference (nor any reasonable combination of the Largent and/or McMillen references) has been shown to provide any articulated basis for imposing a power suitable for near vision in a central portion of one eye and a peripheral portion of the other eye, with the reverse arrangement (a central portion of the other eye and a peripheral portion of the eye) provided with a power for far vision. Hence, claim 27 is now allowable over the cited art.

Regarding independent claims 41 and 42, Applicants respectfully submit that these claims are allowable for many of the reasons given above. Hence, all claims now pending in this application are now in condition for allowance.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

//Mark D. Barrish//

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THE EXCIMER MANUAL

A CLINICIAN'S GUIDE TO EXCIMER LASER SURGERY

JONATHAN H. TALAMO
RONALD R. KRUEGER

The Excimer Manual

A Clinician's Guide to Excimer Laser Surgery

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could result in diplopia should be fully evaluated before keratorefractive surgery. Any history or finding on examination that suggests amblyopia should also be carefully documented.

Pupillary Examination

Pupillary examination should include the measurement of pupillary size, shape, and direct and concentric light responses. Pupil size and shape are especially important when planning the optical zone size for RK or photoablative procedures. Any abnormalities noted with the pupillary light response deserve further evaluation.

Retinoscopy and Manifest and Cycloplegic Refractions

Retinoscopy and manifest and cycloplegic refractions are imperative for assessing refractive stability. Any significant discrepancies among these measurements require further evaluation for the presence of overaccommodation, latent hyperopia, progressive myopia or astigmatism, corneal warpage syndromes, and other corneal, lenticular, or retinal pathology. Refractions should also be compared with the patient's current spectacle correction and with corneal topography. It is also important to record the patient's uncorrected and best corrected visual acuities. As stated previously, refractive stability must be documented before any keratorefractive procedure can be performed.

External Examination

External examination should focus on the lids, lashes, and lacrimal apparati. Any lid abnormalities, such as lagophthalmos, entropion, ectropion, trichiasis, blepharitis, chalazia, or other lid lesions should be treated before planning surgery. Lagophthalmos, ectropion, entropion, and trichiasis can cause problems with corneal exposure and ocular surface instability. Blepharitis, canaliculitis, and dacryocystitis can predispose patients to infection in the perioperative period. Chalazia and other lid lesions can cause astigmatism and corneal warpage syndromes. Obviously, any indication of accompanying systemic medical disease warrants further evaluation.

Slit-Lamp Examination

Slit-lamp examination should include a thorough examination of all anterior segment structures with special attention focused on the conjunctiva, cornea, and lens. Further evaluation of any lid abnormalities noted on external examination should also be included.

Examination of the conjunctiva should detect any scarring from previous trauma, surgery, inflammatory disease, or infection and any conjunctival lesions. The presence of conjunctival pathology can

Issue: May 2004

marketplace

Focus on Pupillometers

NEUROPTICS
BD Ophthalmic Systems

The handheld NeurOptics pupillometer is a self-contained digital camera and microprocessor that objectively measures the diameter of the eye. With the push of a button, it captures and analyzes more than 40 images in approximately 3 seconds while a video tracking system accommodates for eye drift. The resulting measurement is accurate to within 0.1 mm.

The NeurOptics' proprietary targeting system locates and locks onto the pupil position, then measures and audibly confirms a successful measurement. Active guidance markers provide visual feedback to the operator to ensure proper alignment during testing. Measurements can be reviewed by recalling stored digital images from the unit's internal memory. About 100 images can be stored.

The instrument includes an adjustable, internally illuminated LCD, with a menu-driven graphic user interface that lets you input specific information about the patient and then displays the patient's information and measurements on the LCD screen. The data can be transferred wirelessly to a printer, a multiparameter monitor or computer.

BD Ophthalmics says testing has shown that the NeurOptics is consistent from unit to unit, and from operator to operator.

Phone: (800) 237-2174 or (201) 847-7142
Web: www.bd.com/ophthalmology

PUPILSCAN II MODEL 12A
Lombart Instrument

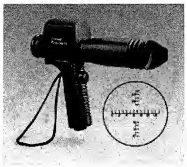
Lombart Instrument says its Pupilscan II Model 12A is as easy to use as point-and-click. The automated, microprocessor-based pupillometer uses an infrared imaging technology to digitize the pupil image, and contains sophisticated software to extract

the diameter of the pupil from the captured image.

Pupil measurement is automated, so no subjective estimates are required. Lombart says automated measurement increases accuracy, reduces the possibility of error, and speeds the measurement process.

With its unique eyecup design, Pupilscan II doesn't require a dark environment to obtain optimum results. With its backlit display, it can be used successfully in nearly any ambient light environment – from room light to total darkness.

Phone (800) 566-2278
E-mail: lombart@lombart instrument.com
Web: www.lombartinstrument.com



COLVARD
Oasis Medical

Oasis Medical offers the Colvard pupillometer, which the company says is ideal for accurately measuring both scotopic pupil size and corneal diameter of cataract and refractive patients prior to surgery.

Using light amplification technology, the Colvard pupillometer allows visualization of the patient's pupils in a darkened exam room. The Colvard features a reticle that provides measurement of the corneal diameter along both the vertical and horizontal axes.

The Colvard is handheld, lightweight and battery-operated, and comes with a storage case, lithium battery and instruction manual.

Phone: (909) 305-5400
E-mail: Sales@OasisMedical.com

PROCYON P3000
Procyon

Introduced in 2001, the original Procyon P2000SA pupillometer from the United Kingdom quickly won acceptance among ophthalmologists for producing accurate measurements. Procyon now introduces its next-generation P3000 pupillometer, which the company says offers even better repeatability, precision and reliability of data. This new unit also features enhancements in patient comfort and improved optical target.

Procyon says the accurate, objective measurements obtained with the P3000 make it ideal for wavefront systems. This is especially true when refractive surgery patients have large pupils and precise pupil data is crucial to the outcome.

Phone: (+44) 1600-750609
E-mail: Duncan@procyon.co.uk
Web: www.procyoninstruments.com

CAPSULORRHEXIS FORCEPS
Rhein Medical introduces its latest microsurgery capsulorrhexis forceps. The Rhein Tubular Capsulorrhexis Forceps has a unique curved shaft for a more comfortable

Rhein Medical's new capsulorrhexis forceps offers a unique curved shaft.

approach to the incision. The special jaws have cystotome tips for pinching and completing the circular tear, and are shorter so as not to interfere with a sub-incisional flap. The tube is 23-gauge, allowing it to pass through a 1-mm incision. The handle is made of ultra-lightweight titanium. The instrument is also autoclaveable, guaranteed for life, and available for a 30-day surgical evaluation without obligation.

Rhein Medical
Phone (800) 637-4346
E-mail: info@rheinmedical.com
Web: www.rheinmedical.com

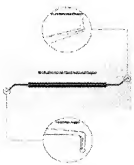
LASIK INSTRUMENT PACK

Moria has launched its new Disposable LASIK Instrument Pack, with each pack containing a disposable, adjustable speculum specifically designed for LASIK, a disposable scraper/hinge protector, and a disposable marker.

The company says use of the new pack eliminates instrument cleaning and damage, as well as potential complications from improperly cleaned or sterilized instruments. The reduced maintenance requirements facilitate faster patient flow and lower overall operating costs.

Used with either the Moria One Use or the new automated One Use-Plus microkeratomes, the disposable instrument pack allows a totally autoclave-free procedure.

Moria
Phone: (800) 441-1314
Web: www.moria-surgical.com



The new Kim Dual Horizontal/Quick Horizontal Chopper was developed by Terry Kim, M.D., of Duke University.

DUAL-PURPOSE CHOPPER

Pelion Surgical of Aiken, S.C., offers the new Kim Dual Horizontal/Quick Horizontal Chopper, an instrument that offers the convenience of two choppers on a single handle.

A traditional-style horizontal chopper is opposite a unique, triangular tip for performing a modified horizontal quick chop. The quick chop tip allows chopping of the nucleus in the horizontal plane from a central location, with traversing peripherally under the anterior capsule. This versatile chopper provides for multiple approaches for nucleus separation.

Tips on both ends have rounded edges to prevent posterior capsule damage. The instrument is made of lightweight titanium and is guaranteed for life against defects in material or workmanship.

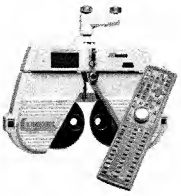
Pelion Surgical
Phone: (888) 883-3991
Web: www.pelionsurgical.com

ELECTRONIC REFRACTOR

Marco has added the wireless Evolution electronic refractor with infrared remote control to its Vision Diagnostic Systems line.

The company says this cost-effective unit gives the practitioner complete control of the refraction process through the convenient remote control.

The practitioner can pre-program the entire refraction process, increasing exam



The Evolution features a remote control.

efficiency. All charts with masks, fogging and other functions can be programmed according to operator preference.

The Evolution offers a 45-degree visual field and high-contrast LCD display. It can also be integrated with chart projectors, autorefractors and lensmeters made by virtually every other manufacturer, eliminating the need for an interface box.

Marco
Phone: (800) 874-5274
Web: www.marcooph.com